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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs For Use In Animal Feeds; Semduramicin and Virginiamycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Pfizer, Inc. The NADA provides for using approved single ingredient semduramicin and virginiamycin Type A medicated articles to make combination drug Type C medicated broiler chicken feeds. Approval of the NADA also provides for tolerances for semduramicin residues and an acceptable daily intake (ADI) for semduramicin and for virginiamycin.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–114 that provides for combining approved Aviax® (22.7 grams per pound (g/lb) semduramicin) and Stafac® (20 or 227 g/lb virginiamycin) Type A medicated articles to make combination drug Type C medicated broiler chicken feeds. The Type C medicated broiler feeds containing 25 parts per million (ppm) (22.7 g/ton (t)) semduramicin and 5 to 15 g/t virginiamycin are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for increased rate of weight gain. The Type C medicated broiler feeds containing 25 ppm semduramicin and 5 g/t virginiamycin are used for

the prevention of coccidiosis caused by *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for increased rate of weight gain and improved feed efficiency. The Type C medicated broiler feeds containing 25 ppm semduramicin and 20 g/t virginiamycin are used for the prevention of coccidiosis caused by *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin.

The NADA is approved as of July 27, 1999. The regulations are amended in 21 CFR 558.555 by redesignating paragraph (b) as paragraph (d), by adding new paragraph (b) and adding and reserving paragraph (c), by revising the heading of newly redesignated paragraph (d), by removing the introductory text of newly redesignated paragraph (d)(1), and by adding paragraphs (d)(5), (d)(6), and (d)(7) to reflect the approval. Also, the regulations are amended in 21 CFR 558.635 by removing paragraphs (a), (c), (e)(3), and (e)(4), by redesignating paragraphs (b), (d), (e), and (f) as paragraphs (a), (b), (c), and (d), by correcting the cross-references in newly redesignated paragraph (a) from paragraph (f) to paragraph (d), by correcting a typographical error in newly redesignated paragraph (d)(2)(i), and by adding paragraph (d)(4)(vii) to also reflect the approval. The basis for approval is discussed in the freedom of information summary.

Furthermore, neither an ADI for semduramicin or for virginiamycin nor a tolerance for semduramicin residues have been previously established. At this time, 21 CFR 556.597 is added to establish an ADI and a tolerance for semduramicin. Also, 21 CFR 556.750 is amended to remove language referring to negligible residues in swine, broiler chicken, and cattle tissues to provide for an ADI for virginiamycin, and to reflect a revised format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.597 is added to read as follows:

§ 556.597 Semduramicin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of semduramicin is 180 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Broiler chickens*. Tolerances are established for residues of parent semduramicin in uncooked edible tissues of 400 parts per billion (ppb) in liver and 130 ppb in muscle.

(2) [Reserved]

3. Section 556.750 is revised to read as follows:

§ 556.750 Virginiamycin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of virginiamycin is 250 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Swine*. Tolerances are established for residues of virginiamycin in uncooked edible tissues of 0.4 part per million (ppm) in kidney, skin, and fat, 0.3 ppm in liver, and 0.1 ppm in muscle.

(2) *Broiler chickens and cattle*. A tolerance for residues of virginiamycin is not required.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

4. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

5. Section 558.555 is amended by redesignating paragraph (b) as paragraph (d), by adding new paragraph (b) and adding and reserving paragraph (c), by revising the heading of newly redesignated paragraph (d), by removing the introductory text of newly redesignated paragraph (d)(1), and by adding paragraphs (d)(5), (d)(6), and (d)(7) to read as follows:

§ 558.555 Semduramicin.

* * * * *

(b) *Related tolerances*. See § 556.597 of this chapter.

(c) [Reserved]

(d) *Conditions of use in broiler chickens*. * * *

(5) *Amount.* Semduramicin 22.7 grams with virginiamycin 20 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix,* and *E. mivati/mitis,* and for prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin.

(ii) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Semduramicin and virginiamycin as provided by 000069 in § 510.600(c) of this chapter.

(6) *Amount.* Semduramicin 22.7 grams with virginiamycin 5 to 15 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix,* and *E. mivati/mitis,* and for increased rate of weight gain.

(ii) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Semduramicin and virginiamycin as provided by 000069 in § 510.600(c) of this chapter.

(7) *Amount.* Semduramicin 22.7 grams with virginiamycin 5 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix,* and *E. mivati/mitis,* and for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Semduramicin and virginiamycin as provided by 000069 in § 510.600(c) of this chapter.

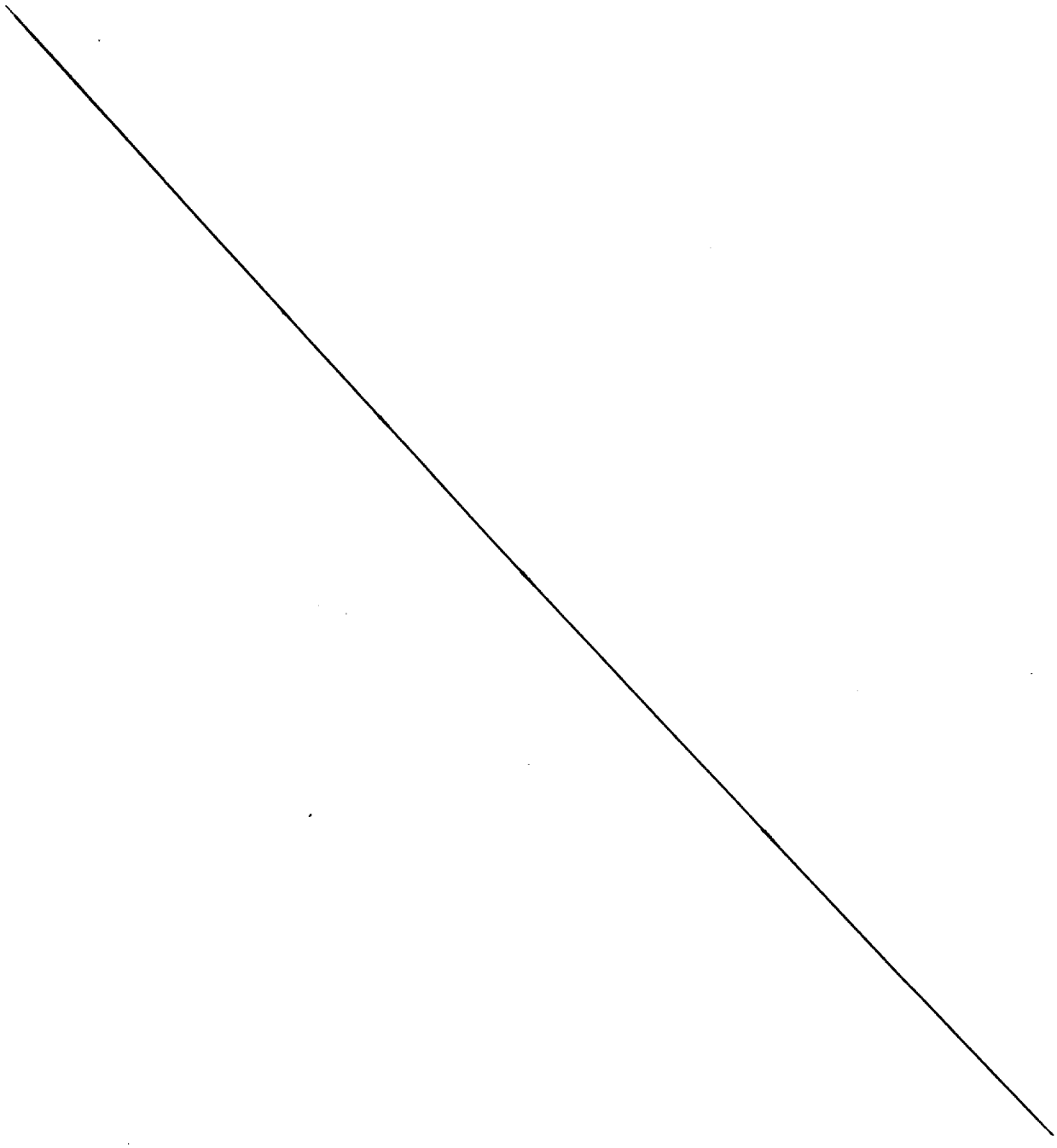
6. Section 558.635 is amended by removing paragraphs (a), (c), (e)(3), and (e)(4), by redesignating paragraphs (b), (d), (e), and (f) as paragraphs (a), (b), (c), and (d), respectively, by removing ''(f)'' and ''(f)(3)'' in newly redesignated paragraph (a)(1) and adding in their places ''(d)'' and ''(d)(3)'', by removing ''(f)(1)(iv)'' and ''(f)(1)(v)'' in newly redesignated paragraph (a)(2) and adding in their places ''(d)(1)(iv)'' and ''(d)(1)(v)'', by removing ''chiickens'' in newly

redesignated paragraph (d)(2)(i) and adding in its place ''chickens'', and by adding paragraph (d)(4)(vii) to read as follows:

§ 558.635 Virginiamycin.

* * * * *

(d) * * *



(4) * * *

(vii) Semduramicin as in § 558.555 of this chapter.

Dated: 8/24/99
August 24, 1999

Stephen F. Sundlof
Director
Center for Veterinary Medicine

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